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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,428	07/10/2003	Scott Schewe	S63.2-10941-US01	3232

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VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
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EXAMINER	
EASHOO, MARK	
ART UNIT	**PAPER NUMBER**
1732	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)
	10/617,428	SCHEWE ET AL.
	Examiner	Art Unit
	Mark Eashoo, Ph.D.	1732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-37,43 and 45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-12,14-28,30-37,43 and 45* is/are rejected.

7)☒ Claim(s) *13 and 29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 10-12, 18 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Pepin et al. (US Pat. 5,614,136) when taken with Chen et al. (US Pat. 6,905,743).

Regarding claim 10: Pepin et al. teaches the claimed process of forming a a polymeric tube segment, comprising: extruding a polymeric tube (Fig. 6); drawing/pulling the tube through a cooling bath (Fig. 6); and altering/varying the drawing rate to change the dimensions in at least two regions or predetermined locations along the tube (3:9-60; 6:5-25, and Fig. 7). Pepin et al. also teaches varying the pressure of the internal air/gas supply during processing to form different tubular segments (5:58-6:48).

Pepin et al. does not specifically teach that different orientations (ie. molecular orientation) occurs during drawing. Nonetheless, it is inherent that axial/longitudinal molecular orientation is proportional is the drawing /pulling rate. This is evidenced by Chen et al. which teaches that a high speed puller imparts a shearing force on a molten/deformable material thereby causing molecular orientation (5: 20-45).

Furthermore it is submitted that by varying the draw rate of the material out of the extruder the speed of the material passing through the gap length inherently changes. Since the "cooling rate" within the gap depends upon the time the extruded tube is within the gap length, it is inherent that the "cooling rate" also changes at this point as the drawing rate changes. Similarly, it the amount of air/gas that enters the gap length is directly proportional to the pressure of the gas. Therefore, the "cooling rate" would change by the amount of air/gas passed through the tube depending upon the pressure used to form each segment.

Regarding claim 11: Pepin et al. also teaches cutting a predetermined locations (Figs. 6-7, element 80).

Regarding claims 12, 21, and 22: Pepin et al. also teaches varying the drawing/pulling rate between at least two different value sets or profiles wherein the wall thickness varies (Figs. 7 exhibits a repeating pattern between two different diameters and Fig. 2a for wall thickness variations).

Regarding claim 18: Pepin et al. also teaches extruding a single polymer (5:63-67).

Regarding claim 20: Pepin et al. also teaches a polymeric blend (8:66-67).

Claims 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Pepin et al. (US Pat. 5,614,136) when taken with Chen et al. (US Pat. 6,905,743).

Regarding claim 23: Pepin et al. teaches the claimed process of forming a a polymeric tube segment, comprising: extruding a polymeric tube (Fig. 6); drawing/pulling the tube through a cooling bath (Fig. 6); and altering/varying the drawing rate to change the dimensions in at least two regions or predetermined locations along the tube (3:9-60; 6:5-25, and Fig. 7). Pepin et al. specifically teaches that the varying the speed of the puller or drawing rate changes the volume of extruded material in a given length (6:5-24) which is essentially the rate of extrusion. Pepin et al. also teaches varying the pressure of the internal air/gas supply during processing to form different tubular segments (5:58-6:48).

Pepin et al. does not specifically teach that different orientations (ie. molecular orientation) occurs during drawing. Nonetheless, it is inherent that axial/longitudinal molecular orientation is proportional is the drawing /pulling rate. This is evidenced by Chen et al. which teaches that a high speed puller imparts a shearing force on a molten/deformable material thereby causing molecular orientation (5: 20-45).

Furthermore it is submitted that by varying the draw rate of the material out of the extruder the speed of the material passing through the gap length inherently changes. Since the "cooling rate" within the gap depends upon the time the extruded tube is within the gap length, it is inherent that the "cooling rate" also changes at this point as the drawing rate changes. Similarly, it the amount of air/gas that enters the gap length is directly proportional to the pressure of the gas. Therefore, the "cooling rate" would change by the amount of air/gas passed through the tube depending upon the pressure used to form each segment.
Regarding claims 24-25: Pepin et al. also teaches varying the drawing/pulling rate between at least two different value sets or profiles wherein the wall thickness varies including tapers or waist portions (Figs. 7 exhibits a repeating pattern between two different diameters and Fig. 2a for wall thickness variations). It is submitted that the high pulling speeds which would cause higher drawing and smaller diameters (ie. at a constant extrusion rate) would experience higher shearing forces and thereby inherently have a higher degree of molecular orientation in these regions relative to the larger diameter regions.

Claims 26-28, 30, 31, 35, 37 and 43-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Pepin et al. (US Pat. 5,614,136) when taken with Chen et al. (US Pat. 6,905,743).
Regarding claims 26 and 43: Pepin et al. teaches the claimed process of forming a polymeric tube segment, comprising: extruding a polymeric tube (Fig. 6); drawing/pulling the tube through a cooling bath (Fig. 6); and altering/varying the drawing rate to change the dimensions in at least two regions or predetermined locations along the tube (3:9-60; 6:5-25, and Fig. 7). Pepin et al. also teaches varying the pressure of the internal air/gas supply during processing to form different tubular segments (5:58-6:48). Lastly, Pepin et al. teaches that process is carried out to "meet required operation and performance characteristics" of the tubular member

(7:15-25), which would be inherently inclusive of yield and break strengths (ie. elongation properties) of the final product.

Pepin et al. does not specifically teach that different orientations (ie. molecular orientation) occurs during drawing. Nonetheless, it is inherent that axial/longitudinal molecular orientation is proportional is the drawing /pulling rate. This is evidenced by Chen et al. which teaches that a high speed puller imparts a shearing force on a molten/deformable material thereby causing molecular orientation (5: 20-45). It is submitted that the high pulling speeds which would cause higher drawing and smaller diameters (ie. at a constant extrusion rate) would experience higher shearing forces and thereby inherently have a higher degree of molecular orientation in these regions relative to the larger diameter regions.

Furthermore it is submitted that by varying the draw rate of the material out of the extruder the speed of the material passing through the gap length inherently changes. Since the "cooling rate" within the gap depends upon the time the extruded tube is within the gap length, it is inherent that the "cooling rate" also changes at this point as the drawing rate changes. Similarly, it the amount of air/gas that enters the gap length is directly proportional to the pressure of the gas. Therefore, the "cooling rate" would change by the amount of air/gas passed through the tube depending upon the pressure used to form each segment.

The examiner recognizes that all of the claimed effects and physical properties are not positively stated by the reference(s). However, the reference(s) teaches all of the claimed ingredients, process steps, and process conditions. Therefore, the claimed effects and physical properties would inherently be achieved by carrying out the disclosed process. If it is applicants' position that this would not be the case: (1) evidence would need to be presented to support applicants' position; and (2) it would be the examiner's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects by carrying out only these process steps.

Regarding claims 27-28 and 44-45: Again, the examiner recognizes that all of the claimed effects and physical properties are not positively stated by the reference(s). However, the reference(s) teaches all of the claimed ingredients, process steps, and process conditions. Therefore, the claimed effects and physical properties would inherently be achieved by carrying out the disclosed process. If it is applicants' position that this would not be the case: (1) evidence would need to be presented to support applicants' position; and (2) it would be the examiner's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects by carrying out only these process steps.

Regarding claims 30-31: Pepin et al. also teaches varying the drawing/pulling rate between at least two different value sets or profiles wherein the wall thickness varies (Figs. 7 exhibits a repeating pattern between two different diameters and Fig. 2a for wall thickness variations).

Regarding claim 35: Pepin et al. also teaches extruding a single polymer (5:63-67).

Regarding claim 37: Pepin et al. also teaches a polymeric blend (8:66-67). It is submitted that a blend requires at least two materials.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pepin et al. (US Pat. 5,614,136) in view of Wand et al. (US Pat. 5,535,388) when taken with Chen et al. (US Pat. 6,905,743).

Regarding claims 14-15: Pepin et al. teaches the basic claimed process as set forth above regarding claim 10.

Pepin et al. does not teach shaping a parison having a variable wall thickness into a catheter balloon. However, Wand et al. teaches shaping a parison having a variable wall thickness into a catheter balloon (2:30-3:25). Pepin et al. and Wand et al. are combinable because they are from the same field of endeavor, namely, the production of medical tubing. At the time of invention a person of ordinary skill in the art would have found it obvious to have shaped a parison having a variable wall thickness into a catheter balloon, as taught by Wand et al., in the process of Pepin et al., and would have been motivated to do so in order to form another product using the same production line (ie. economic benefit).

It is noted that the preform of Wand et al. would require the cuts in Pepin et al. to alternate or skip a cut in a large thickness section, thereby forming a narrow, more oriented, segment that would be considered "proximal" relative to the thicker, less oriented, segment used to form the balloon. In other words, the effective weight of terms "proximal" and "distal" are relative terms depending upon the use of the final product.

Regarding claims 16-17: Pepin et al. also teaches varying the drawing/pulling rate between at least two different value sets or profiles wherein the wall thickness varies (Figs. 7 exhibits a repeating pattern between two different diameters and Fig. 2a for wall thickness variations).

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pepin et al. (US Pat. 5,614,136) in view of Tiernan et al. (US Pat. 6,579,484) when taken with Chen et al. (US Pat. 6,905,743).

Regarding claim 19: Pepin et al. teaches the basic claimed process as set forth above regarding claim 10.

Pepin et al. does not teach co-extruded multilayer tubing. However, Tiernan et al. teaches co-extruded multilayer tubing (abstract and Figs. 7-9). Pepin et al. and Tiernan et al. are combinable because they are from the same field of endeavor, namely, the production of medical tubing. At the time of invention a person of ordinary skill in the art would have found it obvious to have co-extruded multilayer tubing, as

taught by Tiernan et al., in the process of Pepin et al., and would have been motivated to do so in order to form a product having desirable physical properties attributed to each of the materials (eg. lubricity and burst strength).

Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pepin et al. (US Pat. 5,614,136) in view of Wang et al. (US Pat. 5,556,383) when taken with Chen et al. (US Pat. 6,905,743).
Regarding claim 33 and 34: Pepin et al. teaches the basic claimed process as set forth above regarding claim 26.

Pepin et al. does not teach using a polyester/polyether block copolymer or a polyamide/polyether/polyester. However, Wang et al. using a polyester/polyether block copolymer (Hytrel ®) or a polyamide/polyether/polyester (Pebax®) (4:40-67). Pepin et al. and Tiernan et al. are combinable because they are from the same field of endeavor, namely, the production of medical tubing. At the time of invention a person of ordinary skill in the art would have found used a polyester/polyether block copolymer or a polyamide/polyether/polyester in the process of making medical tubing, as taught by Wang et al., in the process of Pepin et al., and would have been motivated to do so because Wang et al. provides evidence that such materials a known equivalents for the same purpose (see MPEP § 2144.06).

Claim 36 is rejected, rendered obvious by Pepin et al. (US Pat. 5,614,136) in view of Tiernan et al. (US Pat. 6,579,484) when taken with Chen et al. (US Pat. 6,905,743).
Regarding claim 36: Pepin et al. teaches the basic claimed process as set forth above regarding claim 26.

Pepin et al. does not teach co-extruded multilayer tubing. However, Tiernan et al. teaches co-extruded multilayer tubing (abstract and Figs. 7-9). Pepin et al. and Tiernan et al. are combinable because they are from the same field of endeavor, namely, the production of medical tubing. At the time of invention a person of ordinary skill in the art would have found it obvious to have co-extruded multilayer tubing, as taught by Tiernan et al., in the process of Pepin et al., and would have been motivated to do so in order to form a product having desirable physical properties attributed to each of the materials (eg. lubricity and burst strength).

Allowable Subject Matter

Claims 13 and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: Applicant's arguments, filed 10/09/06, with respect to claims 13 and 29 are persuasive.

Response to Arguments

Applicant's arguments filed 10/09/06 have been fully considered but they are not persuasive, with the exception of claims 13 and 29, and have been substantially responded to in the rejections set forth above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Eashoo, Ph.D. whose telephone number is (571) 272-1197. The examiner can normally be reached on 7am-3pm EST, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on (571) 272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Eashoo, Ph.D.
Primary Examiner
Art Unit 1732

04 / Jan / 07

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4-Jan-07